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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,426	07/02/2001	Kazutoshi Watanabe	P20810	7478

7055 7590 11/19/2003

GREENBLUM & BERNSTEIN, P.L.C.  
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RESTON, VA 20191

EXAMINER
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TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/19/2003

AF 12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/787,426

Applicant(s)

WATANABE ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment of 8-6-03 has been fully considered. Since claims 1-12 have been cancelled, the previous rejections are no longer applicable to said claims. New compound claims seem to overcome the previous 102 rejections based on various references, and thus said rejection is withdrawn herein. However, the 112/1<sup>st</sup> paragraph can still be applied to new claims 13-41 are pending. Also, new ground of 112/2<sup>nd</sup> rejection is presented herein.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claims 13-15, 17, 18, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of Alzheimer's disease, does not reasonably provide enablement for the treatment of other neurological diseases that are allegedly related to tau protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;

- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

**a. The breadth of the claims:** The breadth of claims 13, and 25 allows for the treatment of neurological diseases that are allegedly related to “tau protein”. Said diseases range from Alzheimer’s to various kinds of Parkinsonism, Down syndrome, and ischemic cerebrovascular accidents, etc. However, for diseases such as Parkinsonisms, Down syndrome, and ischemic cerebrovascular accidents, the state of the art only provides speculations, and not evidence related them to “tau protein”.

**b. The amount of direction or guidance presented:** The specification mainly relates “tau protein” to the production of “amyloid” which is related to Alzheimer’s, but not to other neurological diseases such as: Parkinsonisms, Down syndrome, and ischemic cerebrovascular accidents. There is no evidence that “amyloid” causes Parkinsonisms, Down syndrome, and ischemic cerebrovascular accidents. Even applicant acknowledges on page 28 of the “Remarks/Arguments” that “*various theories have been proposed* [emphasis added] *as for the reason why A $\beta$  causes the cell death, and any authentic theory has not yet been established* [emphasis added].”

c. As stated in the previous action, the **state of the art** relates Parkinson's diseases to dopamine, Down syndrome to the extra chromosome, and ischemic cerebrovascular accidents to atherosclerosis, or plague formed by cholesterol. Said relationships are recognized in the art. Although they may be "other characteristics" of those diseases, they form the scientific basis for current treatment, or no treatment (as in the case of Down syndrome). Furthermore, Parkinson's, Down syndrome, and ischemic cerebrovascular accidents do not share the same symptoms with Alzheimer's disease since the late stage of Alzheimer's disease tends to have violent episodes whereas the other diseases do not.

Therefore, with the **unpredictable nature** of the art, and limited teaching, the skilled clinician will have to carry out undue experimentation to apply the claimed pyrimidone compounds to the treatments of various Parkinsonisms, Down syndrome, and ischemic cerebrovascular accidents.

2. **Lack of Written Description:** Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 19 recites a "method for prophylactic treatment" which does not have a description in term of the timing of administering or the duration of such a "prophylactic treatment". Thus, one cannot tell exactly the steps and procedure for such a method.

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3. **Enablement:** Claims 19-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because it is not clear what the procedure is for a “method for prophylactic treatment”, one skilled in the art cannot practice the claimed method without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 13-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

d. The term “derivative” (wherever recited) has indefinite metes and bounds because one cannot tell with what functional groups variables  $R^1$ – $R^3$  are further substituted, and how extensive is further substitution. Applicant is suggested to replace said term with the term “compound”.

e. The phrase “salt thereof” appears to also encompasses toxic salt. Thus, applicant is suggested to replace said phrase with “pharmaceutically acceptable salt thereof”.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485.

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The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1<sup>st</sup> -03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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November 16, 2003



ALAN L. ROTMAN  
SUPERVISORY PATENT EXAMINER  
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